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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/428,203	10/27/1999	CHRISTOPHER O. OKUNJI	003/172/SAP	4366

7590 03/28/2008  
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EXAMINER
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FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1655

MAIL DATE	DELIVERY MODE
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03/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/428,203	<b>Applicant(s)</b> OKUNJI ET AL.	
	<b>Examiner</b> Michele Flood	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 38 is/are pending in the application.
- 4a) Of the above claim(s) 2-10, 13-29 and 32-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 11, 12, 30, 31 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Acknowledgment is made of the receipt and entry of the amendment filed on November 30, 2007 with the cancellation of Claim 40.

The elected species, namely *Napoleonaea imperialis*, the solvent methanol and the seed portion of the plant, was not found; therefore, the elected invention was searched to the extent that the next species was found.

**Claims 1, 11, 12, 30, 31 and 38 are under examination.**

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 11, 12, 30, 31 and 38, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

Claim 1 is rendered indefinite by the phrase "A biologically active extract comprising a fractionation extract" because it is not clear as to the subject matter to which Applicant intends to seek patent protection. For example, plant material may be initially extracted with either water or methanol as a solvent in the making of a crude plant extract followed by subjecting the crude plant extract to fractionation with one or more solvents of increasing polarity or increasing strength. It would appear that

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Applicant intends to direct the subject matter of the claimed invention to a biologically active extract comprising a fractionated extract from at least one plant selected from the claim-designated Markush group recited in Claim 1. The lack of clarity renders the claim ambiguous.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 12, 30 and 31, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Okunji et al. (U). Newly applied as necessitated by amendment.

Applicant claims a biologically active extract comprising a fractionation extract from at least one plant selected from the group consisting of *Aframomum aulocacarpus*, *Aframomum danielli*, *Dracaena arborea*, *Eupatorium odoratum*, *Glossocalyx brevipes* and *Napoleonaea imperialis*, wherein the extract is obtained using an organic solvent, and wherein the biologically active extract is saponin-enriched and exhibits therapeutic anti-leishmanial activity. Applicant further claims a biologically active extract according to claim 1, wherein the extract is from at least one of roots, stem, bark, leaves, fruits or

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seeds from the plant; wherein the solvent is selected from a group consisting of hexane, chloroform, ethyl acetate and methanol wherein the extract is obtained directly from solvent extraction of powdered seeds of the plant utilizing the solvent. Applicant further claims a biologically active extract according to claim 11, wherein the solvent is methanol.

Okunji teaches a saponin-enriched fraction of a methanol extract of powdered seed pulp obtained from *Dracaena arborea* (see abstract). On page 417, under "*Extraction and Isolation Protocol*", Okunji teaches that the powdered pulp plant material was directly extracted with methanol and that 'a portion of the methanol extract was first partitioned between chloroform-methanol-water mixture to yield a saponin-enriched lower organic layer which was concentrated to dryness *in vacuo* and lyophilized'. Okunji further teaches fractionation of the crude active saponin extract to obtain three spirostanol saponins, designated spiroconazole A, B and C. Okunji demonstrates that spiroconazole A exhibits anti-leishmanial activity (see Figures 4 and 5).

The reference anticipates the claimed subject matter.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood  
Primary Examiner  
Art Unit 1655

MCF  
March 24, 2008  
/Michele Flood/  
Primary Examiner, Art Unit 1655